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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,590	01/08/2001	Stewart Russell Jurgensen	P-4993	5633
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DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880				
EXAMINER TRAN, MY CHAU T				
ART UNIT		PAPER NUMBER		
1639				

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/756,590

Applicant(s)

JURGENSEN ET AL.

Examiner

MY-CHAU T TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/21/2004 has been entered.

Status of Claims

2. Applicant's supplemental amendment filed 9/2/2004 and 9/3/2004 is acknowledged and entered. Claims 39-40, 44-50, and 54-56 have been amended. It is noted that applicant designation of the claims 57-60 are improper since they were previously presented in the amendment filed 9/2/2004. Claims 57-60 should be designated as "previously presented" *not* "new".

3. Applicant's amendment filed 7/21/2004 is acknowledged and entered. Claims 1-38 have been canceled. Claims 39-60 have been added.

4. Claims 4, 6, 10-12, and 23 were canceled; Claims 1, 7, 13, 15, 18-19, and 31 were amended; and Claims 37-38 were added by the amendment filed on 7/18/03.

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5. Claims 23 and 32 were canceled, and Claims 1, 5-7, 19, 21, and 31 were amended by the amendment filed on 12/30/02.

6. Claims 39-60 are pending.

7. Claims 39-60 are treated on the merit in this Office Action.

Withdrawn Rejections

8. The rejection of claims 1, 5-13, and 14-18 under 35 USC 103(a) as being obvious over Levine et al. (US Patent 5,635,362) in view of Van Vlasselaer (US Patent 5,474,687) has been withdrawn in view of cancellation of claims 1-38.

9. The rejection of claims 19-22, and 24-30 under 35 USC 103(a) as being obvious over Levine et al. (US Patent 5,393,674) in view of Van Vlasselaer (US Patent 5,474,687) has been withdrawn in view of cancellation of claims 1-38.

10. The rejection of claims 31, and 33-36 under 35 USC 103(a) as being obvious over Levine et al. (US Patent 5,393,674) in view of Van Vlasselaer (US Patent 5,474,687) has been withdrawn in view of cancellation of claims 1-38.

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11. The rejection of claims 1-18 under 35 USC 103(a) as being obvious over Levine et al. (US Patent 5,393,674) and Van Vlasselaer (US Patent 5,474,687) has been withdrawn in view of cancellation of claims 1-38.

12. The rejection of claims 37 and 38 under 35 USC 103(a) as being obvious over Levine et al. (US Patent 5,635,362; which is now refer to as Levine #1) and Levine et al. (US Patent 5,393,674; which is refer to as Levine #2) has been withdrawn in view of cancellation of claims 1-38.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 39-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 39 is vague and indefinite. Claim 39 recites a method, however the claimed method steps describe a “method for harvesting a target component from a biological sample”. It is unclear what constitutes the metes and bounds as to the ‘type’ of method being claimed in the present invention and thus claim 39 is vague and indefinite.

b. The term "possessing" in claim 39 is a relative term, which renders the claim indefinite. The term "possessing" is not defined by the claim, the specification does not

provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. It is unclear as to the manner in which the microbeads 'possess' the binding agent.

c. The term "capable of" in claim 39 is a relative term, which renders the claim indefinite. The term "capable of" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. It is unclear whether the binding agent is "able" to bind to the components.

d. The term "desired components" in claim 39 is vague and indefinite because it is unclear what constitutes the metes and bounds of "desired", i.e. what is the distinction between "desired" and "undesired"? Is it structure? Or Function?

e. The term "undesired components" in claim 39 is vague and indefinite because it is unclear what constitutes the metes and bounds of "undesired", i.e. what is the distinction between "desired" and "undesired"? Is it structure? Or Function?

f. Claim 39 lacks clear antecedent for the term "sample" in line 8 of step (a) of the claim. The sample of the claim is first referred to as a "biological sample" not a "sample".

g. Claim 39 lacks clear antecedent for the term "sample components" in line 9 of step (a) of the claim. The sample of the claim is first referred to as a "biological sample" not a "sample".

h. The phrase "being capable of elongating layers" is vague and indefinite because it is unclear whether the "focusing device" has the "ability" to "elongate" layers of sample.

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- i. The step (a) and step (b) of claim 39 is confusing regard the type of “elongating layers” of the focusing device. Step (a) refers to the “elongating layer” of the focusing device as the sample components, i.e. can be the desired components, undesired components, or both.
- j. Claim 39 lacks clear antecedent for the term “target” in line 2 of step (b) of the claim. Step (a) of claim 39 has no mention of the term “target”.
- k. Moreover, the term “target” in claim 39 is vague and indefinite because it is unclear whether it is referring to the “desired component” or the “undesired component”.
- l. The phrase “substantially absent” in claim 39 is considered indefinite because it is unclear as to the means of measuring the degree of “substantially”. It is unclear what constitutes the metes and bounds of “substantially absent”, i.e. what degree is considered “substantially absent”? 25%? 50%? 100%?

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 39-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (US Patent 5,776,710; which is refers to as Levine '710) and Levine et al. (US Patent 5,393,674; which is refers to as Levine '674).

Claim 39 recites a method. The method comprises the step of: 1) placing the biological sample into a separation container; 2) centrifuging the separation container containing the biological sample to densitometrically separate components of the biological sample into layers, wherein the elongated target layer is located within the focusing device of the separation container; and 3) aspirating the elongated target layer to remove the desired component from the separation container.

The separation container comprises a) a focusing device, b) a first set of selection microbeads, and c) a second set of selection microbeads. The first set of selection microbeads comprises a binding agent that specifically binds to the target, i.e. desired component, in the biological sample. The second set of selection microbeads comprises binding agent different from the binding agent of the first set of selection microbeads, and specifically binds to components other than the target, i.e. undesired components, in the biological sample. The focusing device has a specific density and upon centrifugation the focusing device move in a vertical direction and elongate the target layer.

The target layer comprises the first set of selection microbeads with the target, i.e. desired components, of the biological sample, and the target layer is elongated within the focusing device. The second set of selection microbeads with the undesired components is not located with the focusing device.

Levine '710 discloses the method for detecting a target analyte in a biological sample in a tube (see e.g. Abstract; col. 2, lines 35-64; claims 1-2). The method comprises the step of a) adding a group of capture bodies to the sample, which capture bodies have a specific gravity which ensures that said capture bodies will settle into a predetermined location in the sample in the tube, each capture body in said group being coupled with a binding material to form capture body couples which are specific to the target analyte; b) adding to said sample labeled antibodies

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or other binding material which are specific to said target analyte so as to form a capture body/labeled binding material sample mixture; c) intimately admixing said sample and said labeled binding material so as to form a capture body/labeled binding material sample mixture; d) incubating the capture body/labeled binding material sample mixture; and e) centrifuging/densimetrically the sample so as to aggregate the capture bodies into a distinct location in the tube (see e.g. Abstract; col. 3, lines 56-58; col. 7, lines 34-57; claims 1-2). The tube comprises one or more bodies or group of bodies such as inserts or plastic beads of different densities (see e.g. Abstract; col. 2, lines 43-49; col. 3, lines 10-15, and 33-37). Additionally, the features of remaining independent and dependent claims are either specifically described by the reference (e.g. type of biological sample), or constitute obvious variations in parameters which are routinely modified in the art (e.g. the density of the microbeads), and which have not been described as critical to the practice of the invention.

The method of Levine '710 differs from the presently claimed invention by failing to include the step of removing the desired component and a ribbed such that one or more axial passages exist in the focusing device.

Levine '674 disclose a method for harvesting target cells from centrifuged sample of blood contained in a tube which also contains a cylindrical float having a through passage for receiving and elongating layers of blood cell components to be harvested from the sample, the float having an axial constant outer diameter which ensures that the float fits snugly in the tube (see e.g. claim 1; fig. 1 and 4). The method steps of centrifuging the blood, tube, and float at sufficient G forces to move the float toward one end of the tube and forcing the blood cell components to settle in said through passage (see e.g. claim 1; fig. 1 and 4). The cells and

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components of the buffy coat layer are expanded linearly in the narrow bore channel in the float and thus can be easily harvested (see e.g. col. 3, lines 13-15). The method includes harvesting the target cells from the float bore (ref. #7 of fig. 5) with a needle (see e.g. col. 4, lines 55-57; fig. 5). Additionally, it is noted that figures 1 and 4 of Levine '674 are identical to figures 1 and 2 of the instant specification.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the step of removing the desired component and a ribbed such that one or more axial passages exist in the focusing device as taught by Levine '674 in the method of Levine '710. One of ordinary skill in the art would have been motivated to include the step of removing the desired component and a ribbed such that one or more axial passages exist in the focusing device in the method of Levine '710 for the advantage of providing a ten fold expansion of the white cell and platelet layers when performing the cell harvesting with the tube-float combination (Levine '674: col. 2, lines 50-60) since both Levine '710 and Levine '674 disclose the method of cell separation by density gradient centrifugation (Levine '710: col. 2, lines 35-64; Levine '674: col. 1, lines 7-14; fig. 1 and fig. 4). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Levine '710 and Levine '674 because Levine '674 claimed the method for harvesting target cells from centrifuged sample contained in a tube which also contains a cylindrical float having a through passage for receiving and elongating layers of components to be harvested from the sample (Levine '674: claim 1 and 2).

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
November 9, 2004


PADMASRI PONNALURI
PRIMARY EXAMINER